WATCHMAN™ Left Atrial Appendage Closure Device

Patient Information Guide

You have recently had a WATCHMAN implant placed in the left atrial appendage (LAA) of your heart. The following information about the WATCHMAN implant is important for you to know, along with medication recommendations and common questions you may have about your implant.

UNDERSTANDING YOUR HEART

This section will discuss the basic function of the normal heart and will also explain what happens when the heart develops atrial fibrillation.

The Normal Heart

The heart is divided into four chambers: two upper chambers called the atria and two lower chambers called the ventricles. The four chambers fill with blood when the heart is at rest and then pump the blood throughout the body with each heart contraction.

The heart has a specialized conduction system which produces electrical impulses that stimulate the heart to contract. Normally, your heart's pumping action is controlled by steady electrical signals that are produced by your heart's natural pacemaker that travel through the atria (the upper chambers) and follow an electrical pathway to the ventricles (the lower chambers). This electrical stimulation causes the heart muscle to contract. The heart then rests and fills with blood until the next contraction occurs. This cycle occurs millions of times in a year.

Atrial Fibrillation and Stroke

In atrial fibrillation, the atria no longer contract in a coordinated fashion and blood may move abnormally as it travels through the upper chambers of the heart. This arrhythmia can cause you to have symptoms like feeling tired, being lightheaded or short of breath, or have a fluttering sensation in your chest. It is also possible that you may have no symptoms at all. The change in how blood flows may also cause blood clots to form within the heart. A blood clot is called a “thrombus” when it is stays in one place. During atrial fibrillation, most of the clots originating in the heart form in a pouch-like structure of the heart connected to the left atrium called the left atrial appendage (LAA), where the movement of blood may become stagnant. If a blood clot, or “thrombus”, were to break loose from the left atrial appendage, it is now called an “embolus” and could travel to another part of the body through the blood stream. If the embolus were to travel to the brain, it could get stuck in a vessel and block the flow of blood to part of the brain. If the blockage is prolonged, oxygen in the blood cannot get through and brain cells can become damaged or die within minutes. This condition is known as a stroke. .A stroke can result in the loss of a body function, weakness, a change in sensation, problems speaking, or even death.

Current Treatment

Doctors may prescribe special medications or perform procedures that try to keep the heart in a normal rhythm to minimize the possibility of atrial fibrillation occurring again. However, these approaches may not be an option for you and they may not work in everyone – sometimes atrial fibrillation may be a permanent condition. Doctors may also prescribe medications (blood thinners) that will lower the risk of stroke by attempting to prevent the formation of blood clots. However, preventing the formation of blood clots due to atrial fibrillation may also result in the body not producing clots when they are necessary, such as after a cut, which may result in an increased risk of bleeding. This bleeding could be minor (like a skin cut taking longer to stop bleeding than normal) or severe (like internal bleeding or bleeding in the skull). Blood thinners or "anticoagulants" may include aspirin, which is typically only used in patients with very low risk of stroke, warfarin, and newer anticoagulants, all of which carry some risk of bleeding.

Other factors may also add to the risk of stroke from atrial fibrillation, such as smoking, high blood pressure, or obesity. Lifestyle changes such as increased physical activity or smoking cessation may also help manage the risk of stroke. Not all strokes are due to atrial fibrillation, but those that happen due to atrial fibrillation tend to be more severe. Not all strokes in patients with atrial fibrillation are due to blood clots from the left atrial appendage and not all strokes can be prevented with anticoagulant therapy.

Why Should I Consider a WATCHMAN Implant?

Your doctor prescribed the WATCHMAN implant for you because you have atrial fibrillation without valvular heart disease, but with other risk factors that put you at an elevated risk of stroke. Although you may take a blood thinner, called warfarin, as an option to reduce the risk of stroke, the WATCHMAN implant may offer an alternative to long-term use of this drug. Since the WATCHMAN implant is permanently in your heart, it may also offer a degree of protection from a thrombus in the left atrial appendage for those times where the use of warfarin may be temporarily interrupted, for example, if you need to undergo surgery and the risk of bleeding requires the blood thinner to be stopped.

The WATCHMAN implant does not cure atrial fibrillation. It is intended to act as a barrier to prevent blood clots from leaving the left atrial appendage, where blood tends to stagnate in atrial fibrillation, and entering the bloodstream where they could cause a stroke. Although most blood clots form within the left atrial appendage, some may form within the body in other places. The WATCHMAN implant does not offer protection from an embolus originating outside the left atrial appendage and so although the risk of stroke is reduced, it is not eliminated.

A thrombus is detected when your doctor takes pictures of your heart with a technique called a TEE (trans-esophageal echocardiogram). A patient with atrial fibrillation who currently has a thrombus within the heart should not be considered for a WATCHMAN implant until the thrombus goes away after a course of blood thinners. Likewise, patients who already have an atrial septal repair or closure device should not be considered for the implant. Other patients who should not be considered would be those with a left atrial appendage that is too large or too small to accommodate the implant. Additionally, due to the upfront risk of undergoing a procedure, patients should not be considered if they are already doing well and anticipate continuing to do well with oral anticoagulants. In general, WATCHMAN is not appropriate for those patients from whom the surgical risk of the implant procedure might be expected to exceed the benefit from receiving the implant. If your atrial fibrillation is due to significant valvular heart disease, the WATCHMAN implant is not recommended as it has not been studied

in that condition and because strokes in this condition often originate from sources other than the left atrial appendage.

Be sure to have a discussion with your doctor about your specific situation as you consider all the options to reduce the risk of stroke to individualize therapy to your own needs.

WATCHMAN Left Atrial Appendage Closure Device

The WATCHMAN Left Atrial Appendage Closure Device is a permanent implant designed to keep harmful blood clots from entering your blood stream and potentially causing a stroke. It is made of materials that are common to many medical devices. The device is designed to be permanently implanted at the opening of the LAA to trap potential blood clots before they exit the LAA.

Implanting the WATCHMAN Device

The WATCHMAN implant is placed into your heart using minimally invasive surgery in a cardiac catheterization laboratory or electrophysiology laboratory by a physician and his/her team. In preparation for the implant, you will be lying on your back on a table while you are continuously monitored throughout the procedure by medical personnel. X-rays and echocardiograms (a special type of ultrasound picture) will be used to help visualize the heart while the implant is being placed and contrast media (dye) will also be injected to help improve the X-ray image. You will be given an anesthetic (either general or local) by your doctor to minimize any discomfort during the procedure. Discuss the anesthesia method that is best for you with your physician.

A small puncture is made into a vein in your groin. A long thin tube, called a catheter, is inserted into the vein and advanced into the right side of the heart (right atrium). Once inside the heart, another puncture is made through a thin muscle wall in the heart so that the catheter can access the left side of your heart (left atrium). A thinner catheter is advanced into the left atrial appendage under X-ray guidance. The WATCHMAN implant is tightly compressed within the catheter and is passed through the catheter into the left atrial appendage. The physician will verify that it is in the right place within the left atrial appendage and then deploy the implant, much like opening up a folded umbrella. After the procedure, the WATCHMAN implant is the only material that remains in the body. In about 45 days, your body will seal over the WATCHMAN implant with a thin layer of tissue.

After the Procedure

After WATCHMAN is implanted, you will rest in the hospital for a short period of time where you will be monitored as you recover. It may be one or more days before you are discharged, and your doctor will determine how long you need to be in hospital.

Your doctor will also have you take warfarin and aspirin after your device has been implanted. After your implant has been in place for a minimum of 45 days, your doctor will take pictures of your heart by means of a test called a TEE (transesophageal echocardiogram) to determine if the implant has closed the appendage. Your doctor ***may*** stop your warfarin medication at that

time, depending on the result of this test. If your doctor chooses to do so, he/she will prescribe clopidogrel instead (a medication that thins your blood) and may increase your aspirin dose.

It is extremely important to follow your medication regimen. If you stop taking these medications or change their dosage before being instructed to do so by your doctor, the chances of blood clot formation, subsequent stroke or even death are increased. Talk to your doctor before stopping your medications or changing their dosage.

If surgery or dental work is recommended which would require you to stop taking these medications prematurely, you and your doctors should carefully consider the risks and benefits of this additional surgery or dental work at this time versus the possible risks from stopping these medications early. Talk to your doctor about the timing of any medical procedures you may need.

If you do require premature discontinuation of these medications because of significant bleeding, your doctor will carefully monitor you for possible complications. Once your condition has stabilized, your doctor may put you back on these medications. Talk to your doctor before restarting medications or changing their doses.

Benefits and Risks

The potential benefits of the WATCHMAN implant for a patient with atrial fibrillation without valvular heart disease are:

- Reducing the risk of stroke from a embolus originating in the left atrial appendage
- Being able to stop long-term warfarin therapy and reduction in the risks associated with long-term warfarin use

In a study of 707 patients that ran for five years (PROTECT AF), the WATCHMAN implant was compared to warfarin. The WATCHMAN implant was found to be as effective as warfarin in reducing the risk of a combination of stroke (either from a blocked vessel or bleeding within the brain), cardiovascular death, or a blood clot creating a blockage in another part of the body besides the brain. A second study of 407 patients (PREVAIL) was conducted for a shorter period of time (about one and a half years) and looked at similar outcomes as PROTECT AF. Although it did not include enough patients and was not conducted for a long enough period of time to show that the WATCHMAN implant was statistically as effective as warfarin, the rates of events were similar to what was seen in PROTECT AF. The study also tested a new training program that was designed for doctors who had not implanted a WATCHMAN device before, and showed that those doctors could safely implant the WATCHMAN device. A follow-on study of 566 patients (CAP) also confirmed that the implant procedure was safe. After these studies were initiated, several new blood thinners were introduced and are available. The WATCHMAN implant has not been compared to these newer medicines.

Although warfarin can help reduce the risk of a blood clot, it also carries other risks, including a risk of bleeding. Across all the clinical trials of the WATCHMAN implant, approximately 95% of patients were able to stop taking their warfarin within six months following a successful implant procedure. In the studies that compared patients who received the WATCHMAN implant to those who continued on warfarin, the long-term risk of bleeding was substantially reduced with the WATCHMAN implant when compared to warfarin.

As with any procedure, there are risks associated with the implant, the associated implant procedure and the medications that are prescribed during and after the implant procedure. You should discuss with your doctor if these risks outweigh the benefit you may receive from a WATCHMAN implant.

Potential adverse events (in alphabetical order) which may be associated with the use of the WATCHMAN implant in the LAA include but are not limited to:

- Air embolism (leak of air bubbles into the bloodstream which may cause damage to organs)
- Airway trauma (damage to your airways)
- Allergic reaction to the contrast dye, anesthetic, WATCHMAN implant material, or medications
- Altered mental status (change in mental status)
- Anemia (thin blood) requiring transfusion
- Anesthesia risk
- Angina (chest pain)
- Anoxic encephalopathy (change in mental status from a lack of oxygen reaching the brain)
- Arrhythmias (heart rhythm abnormalities)
- Atrial septal defect (hole in wall between upper chambers of the heart)
- Arteriovenous (AV) fistula (abnormal connection between your blood vessels)
- Bruising, hematoma (blood collection) or seroma (fluid collection) near the catheter insertion site
- Cardiac perforation (perforation of the heart muscle)
- Chest pain / discomfort
- Confusion post procedure
- Congestive heart failure (decreased ability of your heart to pump blood)
- Contrast-related nephropathy (kidney damage from contrast dye)
- Cranial Bleed (bleeding inside the skull)
- Decreased hemoglobin (lack of red blood cells in your blood)
- Deep vein thrombosis (blood clot in a vein)
- Death
- Damage to or tearing of cardiac tissue (damage to the heart tissue)
- Device Embolization (device moves from the intended location)
- Device fracture (damage to the WATCHMAN implant)
- Device thrombosis (clot on the implant)
- Edema (fluid collection in the tissue)
- Erosion of the device through surrounding tissue
- Excessive bleeding
- Fever
- Groin pain
- Groin puncture bleed
- Hematuria (blood in the urine)
- Hemoptysis (blood in the sputum)

- Hypotension (low blood pressure)
- Hypoxia (low oxygen level in the bloodstream)
- Improper wound healing
- Inability to move or retrieve device
- Inability to recapture the device
- Infection/Pneumonia
- Interatrial septum thrombus (blood clot on wall between heart's upper chambers)
- Intratracheal bleeding (bleeding in the wind pipe)
- Major bleed requiring transfusion
- Misplacement of the device / improper seal of the appendage / movement of the device from appendage wall
- Nausea (feeling sick)
- Oral bleeding (bleeding from the mouth)
- Pericardial effusion / tamponade [accidental heart puncture causing fluid collection in the heart sack (pericardial effusion) which may lead to increased pressure in the heart sack (tamponade)]
- Pleural Effusion (collection of fluid around the lungs)
- Prolonged bleeding from a laceration (prolonged bleeding from a cut)
- Pseudoaneurysm (abnormal connection between your blood vessels due to the procedure)
- Pulmonary Edema (collection of fluid in the lung tissue)
- Pulmonary Vein Obstruction (obstruction of blood vessel from lung)
- Renal failure (kidney failure)
- Respiratory insufficiency/failure (breathing failure)
- Thrombosis (clot formation)
- Stroke – Hemorrhagic (stroke from bleeding inside the brain)
- Stroke – Ischemic (stroke from lack of blood supply to a part of the brain)
- Systemic Embolism
- TEE (Transesophageal echocardiogram) complications (throat pain, bleeding, esophageal trauma)
- Thrombocytopenia (low platelet count)
- Transient Ischemic Attack (TIA) (temporary loss of body function that results from lack of blood supply to part of the brain)
- Valvular or vascular damage (damage to heart valve or blood vessel)
- Vasovagal Reactions (change in blood pressure and/or heart rate)

There may be other potential adverse events that are unforeseen at this time.

Medications

Your doctor has prescribed medication to thin the blood and prevent blood clots from forming. Current guidelines recommend anticoagulation with warfarin to thin the blood and delay clotting (coagulation) in patients with AF. A blood test called the International Normalized Ratio (INR) is used to assess the time it takes for the blood to clot and to determine the correct dose of warfarin. Too high an INR level increases the risk of bleeding. Too low a level increases the risk of clotting. Because the correct warfarin dose may change over time, it's important to test the INR at regular intervals. Your doctor will also have you take aspirin after your device has been implanted. After your implant has been in place for a minimum of 45 days, your doctor ***may*** stop

your warfarin medication as described above. If your doctor chooses to do so, he/she will prescribe clopidogrel and may increase your aspirin dose.

It is extremely important to follow your medication regimen. If you stop taking these medications or change their dosage before being instructed to do so by your doctor, the chances of blood clot formation, subsequent stroke or even death are increased.

Activity

• Follow your doctor's guidelines.
• Return to normal activities gradually, pacing your return to activity as you feel better. Check with your doctor about strenuous activities.
• Let your doctor know about any changes in lifestyle you make during your recovery period.
• Report side effects from medications immediately. These may include bleeding, headaches, nausea, vomiting or rash.
• Do not stop taking your medications, or change their dose, unless you are asked to by the doctor who implanted your device.
• Keep all follow-up appointments, including laboratory blood testing.
• Carry your WATCHMAN™ Closure Device Implant Card at all times. If you receive dental or medical care or report to an emergency room/center, show your Closure Device Implant Card.

Frequently Asked Questions

Can the WATCHMAN implant move or rust?

Once positioned by your physician, the implant should not move on its own. It is manufactured so it will not rust.

Can I walk through metal detectors with the WATCHMAN implant?

Yes, without any fear of setting them off.

How soon can I resume normal daily activities?

The majority of people return to normal daily activities within a few days following the procedure. Check with your doctor before resuming your usual activities.

What if I experience pain?

If you experience pain, immediately inform your doctor or the center where the procedure was performed.

What if I miss taking my medication?

Call your doctor.

Can I undergo MRI or scanner testing with the WATCHMAN implant?

MRI safety testing has shown that the WATCHMAN Left Atrial Appendage Closure Device is "MRI Conditional" and that a patient with a WATCHMAN implant may safely undergo an MRI scan under certain conditions listed on the WATCHMAN Closure Device Implant Card. Prior to undergoing an MRI scan, inform your doctor or MRI technologist that you have a WATCHMAN Left Atrial Appendage Closure Device, and show them the WATCHMAN Closure Device Implant Card.

Indications, contraindications, warnings and instructions for use can be found in the labeling supplied with each product. CAUTION: Federal (U.S.A.) law restricts these products to sale by or on the order of a physician.

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WATCHMAN™ Closure Device Implant Card

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One Boston Scientific Place
Natick, MA 01760-1537USA
USA Customer Service 888-272-1001
www.bostonscientific.com/watchman
Device: WATCHMAN Left Atrial Appendage Closure Device
Patient Name:
Date of Implant:
Device Lot #:
Implanting Physician:
Hospital:
Contact information:

If you require a magnetic resonance imaging (MRI) scan, tell your doctor or MRI technician technologist that you have a left atrial appendage closure implant. Non-clinical testing has demonstrated the WATCHMAN implant is MR Conditional. A patient with a WATCHMAN implant can be scanned safely under the following conditions:

- Static magnetic fields of 1.5 Tesla or 3 Tesla
- Spatial gradient field of 2500 Gauss/cm or less
- The maximum whole body averaged specific absorption rate (SAR) shall be limited to 2.0 W/kg (normal operating mode only) for 15 minutes of scanning
- Normal operating mode of the MRI scanner

The WATCHMAN implant should not migrate in this MRI environment.
MR imaging within these conditions may be performed immediately following the implantation of WATCHMAN. MR image quality may be compromised if the area of interest is relatively close to the WATCHMAN implant. Optimization of MR imaging parameters is recommended. This implant has not been evaluated to determine if it is MR Conditional beyond these parameters.

PLEASE CARRY YOUR CARD AT ALL TIMES.
Your doctor has prescribed medication to thin the blood and prevent blood clots after your implant. It is extremely important to follow the medication regimen as prescribed by your doctor. Before considering any surgery or dental work which would require you to stop taking these medicines early, you and your doctors should consider the risks from premature discontinuation of these medications**. For questions regarding your WATCHMAN implant or other procedures (e.g., MRI), please contact your implanting doctor.**

Follow-up Visit Dates	
45-day visit	
6-month visit	

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